UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,685	04/03/2002	Patricia Anne Nuttall	2488-1-002	6308

23565 7590 09/22/2004

KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,685	NUTTALL ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8-10,16-37 and 40-51* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 22-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10, 16-21 and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 2-3, 8-10, 16-37 and 40-51 are pending.

2. Applicant's election with traverse of Group II, claims 8-13 and 16-21, now claims 8-10, 16-21 and 40-51 in the reply filed on 08/02 /04 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the inventions must be both independent and distinct and an undue search burden on the examiner. However, MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required.

Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria, indicates that inventions recognized divergent subject matter and that a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. All the above establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in the previous Office Action and above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-3 and 22-37 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 8-10, 16-21 and 40-51 read on a recombinant protein derived from a blood-feeding arthropod ectoparasite that inhibits tryptase and a pharmaceutical composition comprising said protein a vaccine comprising said protein and a process for the formulation of a pharmaceutical composition comprising said protein under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 16- 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 16- 21 are indefinite and ambiguous in being dependent upon canceled claim 1.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10, 16-21 and 40-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an the protease inhibitor protein of SEQ ID NO:2, derived from tick *R. appendiculatus* does not reasonably provide enablement for : (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A) The claims as written encompass the genus of recombinant protein amino acid sequences. The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequences.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant discloses a protease inhibitor protein sequence of SEQ ID NO:2, derived from tick *R. appendiculatus* which inhibits tryptase (see page 10 and Fig. 1 in particular).

Applicant has not taught how to make and/or use (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51. The structural and functional characteristics of said recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or active fragment of said protein or functional equivalent of said protein are not defined in the claim. Moreover, the recitation of percent identity language, in the absence of *a testable function* does not allow the skilled artisan to make and use claimed polypeptide commensurate in scope with the instant claims without undue experimentation.

Since the instant fact pattern fails to indicate that representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product.

Applicant is relying upon certain biological activities and the disclosure of a single species to support an entire genus. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Therefore, structurally unrelated use (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51 would be expected to have greater differences in their activities.

Protein chemistry is probably one of the most unpredictable areas of biotechnology . It is known in the art that even single amino acid changes or differences in a proteins amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. (PNAS, 1993. 90: 10056-10060) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular). Burgess et al (J Cell Biol. 111:2129-2138, 1990) show that a conservative replacement of a single "lysine" reside at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Similarly, Lazar et al. (Mol Cell Biol. 8:1247-1252, 1988) teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagines did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and

characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to function as claimed. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions.

Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

In view of this unpredictability; the skilled artisan would not reasonably expect a polypeptide having anything less than 100% identity *over the full length of SEQ ID NO:2* to *share the same function* as the polypeptide of SEQ ID NO:2.

Since the amino acid sequence of a polypeptide determined its structural and functional properties, predictability of which fragments will retain functionality requires knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence contribute to its structure, and therefore, function. The problem of predicting which fragments or derivatives of a protein will retain functionality and which will not is complex and well outside the realm of routine experimentation. Because of the lack of sufficient guidance and predictability in determining which structures would lead to functional proteins or peptides with the desired properties and that the relationship between the sequence of a peptide and it's tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al, in The Protein Folding Problem and Tertiary Structure Prediction, 1994. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of proteins encompassed by the claimed invention. Without sufficient guidance, the changes which can be made in the structure of: (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent

of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51 and still maintained the function of tick-derived protease of SEQ ID NO:2, derived from tick *R. appendiculatus* is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Also, at issue is whether or not the claimed composition would function as pharmaceutical composition, or as vaccine as claimed in claims 18-21. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition/vaccine as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition/vaccine are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition/vaccine with a reasonable expectation of success.

By definition, a vaccine is a composition to induce a specific immunity that **prevent** or protect against a specific disease caused by a specific agent. One of the criteria for a vaccine is the levels of antibody (humoral immune response) before and after immunization and the success of vaccination is judged by the extent of increase in the level of antigen - specific antibody. The second criterion for a vaccine is the ability to stimulate memory T lymphocytes (cell-mediated immune response) (See Immunobiology, Third Edition, Chapter 13 in particular). The specification provides no information on the immunogenicity of *any* vaccine comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase or the ability of such vaccine to protect or prevent from a specific disease. The specification fails to teach that the vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase are capable of generating an antibody response. The specification also fails to teach that the antibody response to the claimed *any* cytokine-coated cell comprising antigen thereof, alone or in combination with adjuvants or carriers provides for a protection against infection. Vaccines by definition trigger an immunoprotective response in the host vaccinated and mere antigenic response is insufficient. It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis,

R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". Moreover, Chandrasheker et al., (US Patent 6,248,329) teach that although many investigators have tried to develop vaccines based on specific antigens, it is well understood that the ability of an antigen to stimulate antibody production does not necessary correlate with the ability of the antigen to stimulate an immune response capable of protecting an animal from specific disease, associated with said antigen (see column 1, lines 35-45 in particular).

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 8-10, 16-21 and 40-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : protease inhibitor protein of SEQ ID NO:2, derived from tick *R. appendiculatus.*

Applicant is not in possession of : (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51.

The claimed invention is drawn to a genus of an isolated recombinat protein derived from a blood-feeding arthropod, however, structural identifying characteristics of the genus are not disclosed. There is no evidence that there is any *per se* structure/function relationship between the disclosed protease inhibitor protein of SEQ ID NO:2, derived from tick *R. appendiculatus.* and (i) any recombinant protein derived from blood-feeding arthropod ectoparasite or from tick, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein as claimed in claim 8-10 and 45-49 or (ii) any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase genetically or chemically fused to one or more peptides, or bound to a support, such as resin , as claimed in claims 16 and 17; or (iii) any pharmaceutical composition or any vaccine composition, comprising any recombinant protein, protein fragment or functional equivalent of any recombinant protein derived from blood-feeding arthropod ectoparasite that inhibits tryptase, as claimed in claims 18-21; or (iv) any recombinant protein that exhibits significant sequence homology, wherein said homology is 50%, 60% and 75 % with the tick-derived protease inhibitor protein set forth in SEQ ID NO:2, or comprising the TdPI sequence, as claimed in claims 40-44; or (v) any anti-tryptase agent or any anti-inflammatory agent comprising recombinant protein derived from blood-feeding arthropod ectoparasite, that inhibits tryptase or any active fragment of said protein or any functional equivalent of said protein, as claimed in claims 50 and 51.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of an isolated polypeptide sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. No claim is allowed.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
September 9, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600